Laparoscopic adnexectomy for benign tubo-ovarian disease using abdominal wall lift: a comparison to laparotomy

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of gasless laparoscopic adnexectomy for benign tubo-ovarian disease, using an abdominal wall-lifting device.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all women having a gasless adnexectomy performed by the author between February 1997 and December 2001. The inclusion criteria were a benign ovarian tumour or tubal pregnancy with stable vital signs, and a body mass index of less than 30 kg/m2. The exclusion criteria were:

- clinical history, examination and ultrasound suggestive of malignancy and therefore requiring laparotomy;
- evidence of cancer following initial diagnostic laparoscopy;
- adnexae that could not be safely mobilised; and
- inadequate operating field.

Setting
The study was conducted in a tertiary care facility, that is, a university hospital in Thailand.

Dates to which data relate
The effectiveness evidence and the aggregated cost data were collected between February 1997 and December 2001. The price year was not stated.

Source of effectiveness data
The evidence for the final outcomes was derived from a single study.

Link between effectiveness and cost data
The costing was carried out on the same patient sample as that used in the effectiveness study. The authors did not state when the cost data were collected for the intervention group, but the costing was carried out retrospectively on the control group.
Study sample
No details about the determination of the sample size were given. The intervention group appears to have been a convenience sample of all women having a gasless adnexectomy performed by the author, according to the inclusion and exclusion criteria (n=65). Three of the 68 laparoscopies (4.4%) were excluded because of severe intestinal adhesion and inadequate operating field. The control population comprised 65 women treated with laparotomy by the author and five colleagues. The records for the control group were matched retrospectively to the study population on indication, procedure and degree of surgical difficulty, and were evaluated retrospectively. All patients were treated in the public sector.

Study design
This was a single-centre, non-randomised, open, cohort study with concurrent controls that were identified retrospectively. The patients were followed from the time of surgery until the 4-week postoperative visit. No patients were lost to follow-up. The assessment of the outcomes was unblinded.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis with no patients being lost to follow-up. The primary health outcomes measured were:

- the operating time,
- complications,
- the postoperative antiemetic dose,
- the lowest percentage oxygen saturation during surgery,
- postoperative stay,
- postoperative recovery period,
- the postoperative parenteral analgesic dose,
- blood loss, and
- febrile morbidity.

The groups were comparable at baseline in terms of age, parity, menopause, body mass index, diameter of ovarian cyst, surgical indications and pathology.

Effectiveness results
The results are presented as mean values plus or minus (+/-) the standard deviation (SD), or as percentages. There were no significant differences in the following outcomes.

Operating time was 81.7 (+/- 14.3) minutes in the study group (gasless laparoscopy) versus 77.1 (+/- 17.5) minutes in the control group (laparotomy), (p=0.108).

There were 4 complications in the study group and 5 in the control group, (p=0.730).

The postoperative antiemetic dose was 3.5 (+/- 5.7) mg in the study group versus 6.3 (+/- 10.1) mg in the control group, (p=0.057).

The lowest oxygen saturation during surgery was 99.1% (+/- 0.8) in the study group versus 99.1% (+/- 0.6) in the control group, (p=0.889).
There were significant differences in the following outcomes.

Postoperative stay was 2.0 (+/- 1.0) days in the study group versus 4.0 (+/- 1.4) days in the control group, (p<0.0005).

The postoperative recovery period was 1.0 (+/- 0.3) week (study group) versus 3.0 (+/- 0.3) weeks (control group), (p<0.0005).

The postoperative parenteral analgesic dose was 11.5 (+/- 20.8) mg (study group) versus 151.8 (+/- 86) mg (control group), (p<0.0005).

Blood loss was 49 (+/- 37) mL (study group) versus 122 (+/- 128) mL (control group), (p<0.0005).

Febrile morbidity was 2 (study group) and 15 (control group), (p=0.001).

**Clinical conclusions**

The study demonstrated that gasless laparoscopic adnexectomy for benign adnexal pathology can be performed as quickly, safely and effectively as laparotomy. In addition, it has the advantages of decreased postoperative pain, hospital stay and recovery time.

**Measure of benefits used in the economic analysis**

No measure of benefits was synthesised. In effect, a cost-consequences analysis was performed.

**Direct costs**

The total hospital charges were reported. These included hospital room, operating room, anaesthesia and medication charges. The resource use quantities and the unit costs were not reported separately. The cost data were collected over the period from February 1997 to December 2001, based on hospital charges in the public sector without additional professional fees. However, it was not stated which years the costs related to and whether they were discounted or reflated. The cost of new reusable equipment was not itemised as a cost, nor were details of its attribution per operation discussed. Although the authors described additional training in the procedure, the cost of it was not explicitly included in the costs. The price year was not stated.

**Statistical analysis of costs**

The costs were treated stochastically and were expressed as the mean value +/- SD. The costs were compared using Student's t-test for continuous variables, and chi-squared or Fisher's exact test for discrete variables. The significance level was 0.05%. The statistical analysis was conducted using SPSS software.

**Indirect Costs**

The indirect costs were not included in the analysis.

**Currency**

The costs were expressed in US dollars ($). The exchange rate was $1.00 = Baht 43.00.

**Sensitivity analysis**

No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**

See the 'Effectiveness Results' section.
Cost results
The total hospital charges associated with inpatient stay were $293.9 (+/- 53.5) for the study group versus $272.7 (+/- 58.4) for the control group, (p=0.033). The costs of treating adverse effects such as emesis and pain were included in the analysis.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
The study demonstrated that gasless laparoscopic adnexectomy for benign adnexal pathology can be performed as quickly, safely and effectively as laparotomy, with a minimal increase in hospital charges. In addition, it has the advantages of decreased postoperative pain, hospital stay and recovery time.

CRD COMMENTARY - Selection of comparators
Laparotomy was chosen as the comparator because it is the standard operating procedure in Thailand for the excision of an ovarian cyst and/or fallopian tube. Carbon dioxide (CO2) laparoscopy, which is widely used in the developed world, was also discussed. CO2 laparoscopy was not chosen as the comparator because the much higher instrumental costs and increased operative time compared with laparotomy have limited its use in Thailand. You should determine if these technologies are relevant to your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the measure of effectiveness was compromised somewhat by the design of the study, which was a non-randomised open cohort study conducted in a single centre with concurrent controls identified retrospectively. This design is less robust than a randomised controlled study. However, this study design was selected because of limitations in patient numbers. The groups were similar in all the characteristics compared. The patients included in the study fulfilled the same entry criterion, that is, designated a candidate for gasless adnexectomy. The sample appears to have been representative of the population of interest in Thailand. The authors acknowledged the limitations of the study design and suggested that the study outcome should be viewed as preliminary. The health outcomes were obtained directly from the effectiveness analysis. The statistical analysis, to compare baseline characteristics and study outcomes, was appropriate.

Validity of estimate of measure of benefit
The estimates of effectiveness were not aggregated into a measure of health benefit. In effect, the study was a cost-consequences analysis.

Validity of estimate of costs
The costs were presented as total hospital charges to proxy costs. They were not disaggregated into unit costs and resource use, although the operative time and duration of inpatient stay was stated. The authors pointed out that the additional equipment cost associated with laparoscopy, including reusable items (e.g. telescope, light source), was responsible for the increased cost associated with gasless laparoscopy. They did not indicate how this cost was attributed to individual operations. Neither was it clear whether the cost of the additional training necessary was included, and if so how it was attributed. The costing took place over a 4-year period, but the year of the costs and whether deflation was applied were not stated. The costs were expressed in US dollars and, while the conversion rate was stated, the date of the conversion rate was omitted. The authors suggested that better outcomes of gasless adnexectomy (including decreased postoperative pain, hospital stay and recovery time) are achieved at a minimal cost of $21 (less than 10% increase in the overall cost), but they failed to put the increase in context. They also did not show whether or not this is a substantial increase in cost in the setting of a developing country.
Other issues
This was a useful study that demonstrated beneficial health outcomes of gasless adnexectomy in comparison with laparotomy for benign tubo-ovarian disease, at minimal increased cost in a developing country. However, the usefulness of the study was limited by its design (cohort design rather than a randomised controlled trial), the insufficient detail on the costing methodology, and the lack of a sensitivity analysis.

Implications of the study
As the study was of a cohort design rather than a randomised controlled trial, the authors recommended that the findings be considered preliminary and the conclusions be evaluated within the known limitations of this study design. The authors suggested that this technique might be an alternative treatment in the developing world where surgical costs and prolonged operation times are a major concern. Since gasless adnexectomy was significantly more expensive and had a longer operating time than laparotomy, the authors in this case were presumably comparing gasless adnexectomy with CO2 laparoscopy, although this was not the comparator in the study. Gasless adnexectomy can provide advantages over conventional laparotomy with minimal increases in hospital charges.

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None stated.

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Other publications of related interest


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